**DOCKET NO.:** CRDS-0062 (CRD0931CIP) **PATENT** 

**Application No.:** 10/829,074

Office Action Dated: February 22, 2007

This listing of claims will replace all prior versions, and listings, of claims in the application.

## **Listing of Claims:**

## 1-14. (canceled)

- 15. (Currently amended) A drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and from about 64 µg to about 197 µg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 and is incorporated into the polymeric coating, wherein said device provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography.
- 16. (Previously presented) A drug delivery device according to claim 15 that provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.3 mm, as measured by quantitative coronary angiography.
- 17. (Previously presented) A drug delivery device according to claim 15 or 16 that provides an in-stent diameter stenosis at 12 months following implantation in a human of less than about 22%, as measured by quantitative coronary angiography.
- 18. (Previously presented) A drug delivery device according to claim 17 that provides an in-stent diameter stenosis at 12 months following implantation in a human of less than about 15%, as measured by quantitative coronary angiography.
- 19. (Currently amended) A drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and <u>from about 64</u> μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said device provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.

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20. (Previously presented) A drug delivery device according to claim 19 that provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.

- 21. (Previously presented) A drug delivery device according to claim 19 or 20 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.
- 22. (Previously presented) A drug delivery device according to claim 21 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 15%, as measured by quantitative coronary angiography.
- 23. (Currently amended) A method of inhibiting neointimal proliferation in a human coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said method provides an instent late loss in diameter at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.
- 24. (Previously presented) A method according to claim 23 that provides an in-stent late loss in diameter at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.
- 25. (Previously presented) A method according to claim 23 or 24 that provides an instent diameter stenosis at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.

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26. (Previously presented) A method according to claim 25 that provides an in-stent diameter stenosis at 12 months following implantation of less than about 15%, as measured by quantitative coronary angiography.

- 27. (Currently amended) A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said method provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.
- 28. (Previously presented) A method according to claim 27 that provides a mean instent late loss in diameter in a human population at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.
- 29. (Previously presented) A method according to claim 27 or 28 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.
- 30. (Previously presented) A method according to claim 29 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 15%, as measured by quantitative coronary angiography.
- 31. (Currently amended) The drug delivery device according to any one of claims 15, 16, 18 or 19 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 64  $\mu$ g to about  $\frac{197 \mu g}{\mu}$  125  $\mu$ g.

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32. (Canceled) The drug delivery device according to claim 31 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 64 µg to about 125 µg.

- 33. (Currently amended) The drug delivery device according to elaim 31 to any one of claims 15, 16, 18 or 19 that releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.
- 34. (Previously presented) The drug delivery device according to any one of claims 15, 16, 18 or 19 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 2 µg to about 30 µg per millimeter of stent length.
- 35. (Previously presented) The drug delivery device according to claim 34 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 3 µg to about 13 µg per millimeter of stent length.
- 36. (Previously presented) The drug delivery device according to claim 34 that releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.
- 37. (Newly added) The method according to any one of claims 23, 24, 27 or 28, wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about  $64 \mu g$  to about  $125 \mu g$ .
- 38. (Newly added) The method according to any one of claims 23, 24, 27 or 28, wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 2 µg to about 30 µg per millimeter of stent length.

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39. (Newly added) The method according to any one of claims 23, 24, 27 or 28, wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 3 µg to about 13 µg per millimeter of stent length.

40. (Newly added) The method according to any one of claims 23, 24, 27 or 28, wherein said drug delivery device releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.